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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/870,544  | 05/30/2001  | R. Rox Anderson      | 910000-2001         | 1057             |
| 21874   | 7590        | 09/08/2005           | EXAMINER            |                  |
| EDWARDS & ANGELL, LLP<br>P.O. BOX 55874<br>BOSTON, MA 02205 |             |                      |                     | FARAH, AHMED M   |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
|   |             | 3739                 |                     |                  |

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/870,544             | ANDERSON ET AL.     |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Ahmed M Farah          | 3739                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 June 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4,6-23 and 25-50 is/are pending in the application.
- 4a) Of the above claim(s) 40-45 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4,6-23,25-39 and 46-50 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-23, 25-39 and 46-50 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Zavislans et al. U. S. Patent No. 5,860,967 in view of Sinofsky U.S. Patent No. 5,071,417.

As to claims 1, 15, 16, 20, 34, 35, 39, 46, and 48-50, Zavislans et al. disclose apparatus and method for non-invasively identifying and locating one or more subsurface targets based on predetermined conditions for selective laser treatment at a tissue surface, the apparatus comprising:

- means for directing one of polarized and an unpolarized light having a predetermined wavelength at a tissue site (see Fig. 3);
- means (CCD camera) for detecting one or more reflections of light using a multi-dimensional photo-sensor;
- means for determining and/or displaying the location and one or more characteristics of the subsurface tissue based upon the detected reflections (see the abstract); and

means (laser **20** and laser controller **24**) for selectively treating one or more subsurface targets using a laser beam of a predetermined wavelength and power in accordance with the tissue characteristics.

As to claims 2, 3, 21 and 22, the determined characteristics include at least the size, shape, and photometric properties of the tissue at one or more subsurface targets.

As to claims 4-6 and 23-25, the controller means **24** pulses the laser beam and adjusts one or more parameters of the laser beam, such as spot size, pulse width, etc.

As to claims 7, 8, 26 and 27, the spot size of the laser beam is adjusted through the movement of focusing lens **42**.

As to claims 12 and 31, the feedback system is controlled by both the operator and computer system. Hence, it is a semi-automatic feedback control.

As to claims 13 and 32, the spot size used by Zavislán et al. is about 500 microns, which is less than 3 mm (see col. 4, lines 58-64).

As to claims 18, 37 and 47, the system of Zavislán et al. further comprises a means for determining a polarization of one or more reflections, wherein the location and one or more characteristics of the subsurface target are determined based upon said polarizations as presently claimed (see col. 6, lines 1-11).

As to claims 19 and 38, the treatment laser beam heats the target tissue thereby modifying the characteristics of said tissue.

However, although the controller system of Zavislán et al. is capable to provide a real time adjustment of the treatment laser in accordance with a desired treatment, they

do not particularly teach a closed loop system as recited. Nevertheless, the use of a feedback control system for non-invasive treatment of a patient is known in the art.

Sinofsky discloses a system and method of use for fusion of biological tissue, the system comprising:

means for directing a laser light (one of polarized and an unpolarized light) having a predetermined wavelength at a tissue site, said laser light heating the tissues at the target site;

means (reflectance monitor 18) for detecting one or more reflections of light using a multi-dimensional photo-sensor;

means (display 24) for determining and/or displaying the location and one or more characteristics of the subsurface tissue based upon the detected reflections (see Fig. 1); and

means (controller 16, laser 12, and tuner 26) for selectively treating one or more subsurface targets using a laser beam of a predetermined wavelength and power in accordance with the tissue characteristics.

As to claims 9, 11, 28 and 30, the reflectance monitor performs real time monitoring/tracking of the target tissue; and the laser delivery unit 20 directs the treatment laser in response to the detected signals. Therefore, in the system of Sinofsky, the directing, detecting, and the determining functions are performed in real time (i.e., rapid feedback for tracking rapid relative movement between the treatment system and target site).

As to claims 10 and 29, the rapid feedback has a bandwidth of more than 0.5 HZ. This is due to the fact that for the tracking to be in real time, the response time of the system (the time between the detection of the reflected system, analyzing the data, and determining the tissue parameter, such as its location) must be much less than 2 seconds. Therefore, even if the response time is about 1 second, the rapid feedback has a bandwidth of 1 HZ, which is more than the recited 0.5 Hz.

As to claims 14 and 33, Sinofsky teaches that his invention is practiced with a wide variety of laser sources, including continuous wave ("c.w.") or pulsed modes (see col. 4, line 68 to col. 5, line 2).

As to claims 17 and 36, the feedback control is one of a closed-loop and quasi-closed-loop feedback control as presently claimed.

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to use a closed loop system to adjust, in real time, at least one or more parameters of the treatment energy in accordance with the desired treatment so as to reduce treatment time. The use of a feedback control, closed-loop system would obviate the need of manual errors and operator delays.

### ***Response to Arguments***

Applicant's arguments filed June 10, 2005, have been fully considered but they are not persuasive. The applicant makes the following arguments/remarks:

The applicant states that the claimed invention, as amended, defines a method and apparatus for selective treatment of a tissue by "determining a location and one or

more characteristic for one or more subsurface targets based upon one or more reflections detected by a photo-sensor and predetermined conditions, wherein the predetermined conditions are defined at least in part by one of predetermined image analysis and one or more programmed mathematical treatment algorithms." In addition, the applicant argues that the prior art of record fails to disclose or suggest, either a system or method of selective laser treatment of a tissue in which the location and one or more characteristic for one or more subsurface target is determined based upon a predetermined conditions and reflections from the target tissue, wherein said location and characteristics "are defined by either predetermined image analysis or one or more mathematical treatment algorithms."

In response to these arguments/remarks, Zavislans discloses a dermatological system and methods of use in which predetermined conditions of the skin, such as destroying endothelial cells in blood vessels, spider veins in the skin, etc., are treated.

In this Office Action, the term 'predetermined condition' of a tissue is treated as a known or identified condition of a tissue/skin in which a desired treatment is directed to. Hence, since Zavislans identifies the tissue condition being treated (for example, the treatment of spider veins), the Examiner's position is that Zavislans teaches the recited treatment elements/steps (i.e., a device and method for 'for selective treatment of a tissue by determining a location and one or more characteristic for one or more subsurface targets based upon predetermined conditions').

As to the recitation 'wherein the predetermined conditions are defined at least in part by one of predetermined image analysis,' Zavislans's system comprises an

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illumination device for illuminating the treatment site, and an imaging device for providing a high-resolution image of the treatment site. Hence, Zavislán determines the treatment condition at least in part by analyzing/viewing the treatment site before, during, and/or after the treatment procedure.

As to the argument that Zavislán fails to teach a method 'for determining the location and a characteristic of the tissue based upon reflections from the target tissue, wherein the location and a characteristic are defined by mathematical treatment algorithms,' the Examiner agrees with the applicant. However, the applicant's written description teaches that the method of analyzing the reflected signal to determine said location and/or characteristic is a known spectroscopic technique (see paragraph 8, lines 7-10 of the specification). Sinofsky clearly teaches a spectroscopic method for determining and/or monitoring a tissue condition from a signal reflected from a tissue at a treatment site (see Figs. 9 and 10 of Sinofsky). Therefore, the examiner's position is that one skilled in the art would employ any of the known spectroscopic techniques to analyze a reflectance signals from the treatment site so as to determine a condition and/or characteristics of the tissue being treated. Furthermore, since the Zavislán's system could be automated (see col. 2, lines 18-22), one skilled in the art could have used a closed loop system to prevent human error and/or to shorten treatment duration.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M. Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ahmed M Farah  
Primary Examiner  
Art Unit 3739

August 27, 2005.

